**INVESTIGATOR COMPLIANCE SEARCH FORM**

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| **ICON Project Number:** | 0078-0609 | **Sponsor Protocol No.:** | IM103116 |
| **Principal Investigator**  **Name:** | Donald Hricik, MD | **Address:** | **University Hospitals Cleveland Medical Center**  **11100 Euclid Avenue**  **Cleveland , OH 44106 / USA** |
| **Medical License Number (if applicable)** | 35.047761 |  |  |

**Please list all relevant sources of Investigator information, against which this Investigator has been checked.**

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| **SOURCE #** | **SOURCE NAME** | **SOURCE DATE** | **WEBLINK** | **ISSUES IDENTIFIED** |

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| 1. | FDA DEBARMENT LIST | 04 Apr 2016 | <http://www.fda.gov/ora/compliance_ref/debar/default.htm> | No | Yes |
| 2. | CLINICAL INVESTIGATOR INSPECTION LIST (CLIIL) (CDER) | 22 Sep 2016 | <http://www.accessdata.fda.gov/scripts/cder/cliil/index.cfm> | No | Yes |
| 3. | FDA WARNING LETTERS and RESPONSES | 06 Dec 2016 | <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm> | No | Yes |
| 4. | NOTICE OF OPPORTUNITY FOR HEARING (NOOH) – PROPOSAL TO DEBAR | 29 Nov 2016 | <http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/ucm143240.htm> | No | Yes |
| 5. | ADEQUATE ASSURANCES LIST FOR CLINICAL INVESTIGATORS | 24 Apr 2014 | <http://www.fda.gov/ora/compliance_ref/bimo/asurlist.htm> | No | Yes |
| 6. | CLINICAL INVESTIGATORS – DISQUALIFICATION PROCEEDINGS (FDA DISQUALIFIED/RESTRICTED) | 05 Dec 2016 | <http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true> | No | Yes |
| 7. | PHS Administrative Actions Listing | 06 Dec 2016 | <http://ori.hhs.gov/misconduct/AdminBulletinBoard.shtml> | No | Yes |
| 8. | Clinical Investigator Inspection List (CBER) | 27 Oct 2016 | <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm195364.htm> | No | Yes |
| 9. | HHS/OIG/ EXCLUSIONS DATABASE SEARCH/ FRAUD | 07 Nov 2016 | <http://exclusions.oig.hhs.gov/> | No | Yes |
| 10. | HHS/OIG Corporate Integrity Agreements/Watch List | 18 Nov 2016 | <http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp> | No | Yes |

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| 11. | SAM/SYSTEM FOR AWARD MANAGEMENT | 11 Nov 2016 | <https://www.sam.gov/portal/public/SAM> | No | Yes |
| 12. | LIST OF SPECIALLY DESIGNATED NATIONALS | 02 Dec 2016 | <http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx> | No | Yes |
| 13. | World Check (Only for PI) | 07 Dec 2016 | http://www.truthtechnologies.com/ | No | Yes |

**If issues are identified (Yes checked above), please provide additional details. Details may be printed and attached.**

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| **SOURCE #** | **DATE OF INSPECTION/ ACTION** | **DESCRIPTION OF FINDINGS** |
| 2 | 12 October 2001  Donald Hricik, MD  ID # 388802  DA / VAI / 03 / 04 | **DA**  - **Data Audit:** An inspection in which the focus is on verification of study data  **VAI** - Voluntary Action Indicated.  Objectionable conditions were found but the problems do not justify further regulatory action. Any corrective action is left to the investigator to take voluntarily.  **03** Inadequate informed consent form 21 CFR 50.25  **04** Inadequate drug accountability 21 CFR 312.60, 312.62 |

**Search Performed By:**

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| --- | --- | --- | --- | --- |
| **Printed Name:** |  | **Signature:** |  | **Date:** |